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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/852,966 | 05/10/2001 | Rima Kaddurah-Daouk | AVZ-020CN | 5588 |

959 7590 08/28/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

KIM, VICKIE Y

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1614

DATE MAILED: 08/28/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,966

Applicant(s)

KADDURAH-DAOUK, RIMA

Examiner

Vickie Kim

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-36, drawn to a method of treating a subject for skin disorder comprising administering to said subject an effective amount of creatine compounds.
 - II. Claims 37-67, drawn to a composition comprising an effective amount of creatine compound(s).
2. Inventions I and II are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products(compositions) as claimed are used in a plurality of patentably distinct uses, as evidenced by numerous US patented literatures. And the process of use(i.e. treating skin disorders such as wrinkles, ageing, etc) are achieved by materially different products as evidenced by numerous patented or non-patented literatures.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II obvious, absent ancillary

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art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper.

3. According to the election of the invention (group I or II), applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Election of species

4. Claim 1 is generic to a plurality of disclosed patentably distinct species comprising a skin disorder as recited in the claims 6-11 (e.g free radicals, aging, sun radiation). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

5. Claims 12 is generic to a plurality of disclosed patentably distinct species comprising a creatine compound of the formula and the preferred species are recited in the claims 16-25. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 26 and 35 are generic to a plurality of disclosed patentably distinct species comprising a creatine compound that is further combined with a second active agent(i.e a skin preserving agent or sunscreen(or sunblock)). Depending upon the election of species, if the skin preserving agent is elected, it is subject to further election

requirement where the species of the said agent has recited in the claims 28-32 the preferred species are recited in the claims 16-25. For example, claim 28 and 30 are patentably distinct, each from the other, as they have acquired a separate status in the art and/or require independent searches. It is noted that a reference to one combination of drugs would not be a reference to another combination of drugs under U.S. C. 103. Further, the claims read on a multitude of enhanced combinations of drugs which would require many field of searches that would be an undue burden on the examiner. Therefore, restriction for examination purposes is proper. MPEP 803.02.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or

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relating to the status of this application or proceeding should be directed to the
receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'Vickie Kim', with a long horizontal flourish extending to the right.

Vickie Kim,
Patent examiner
August 26, 2002
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